



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,339	08/03/2000	Carl T Wittwer	7475-66667	9681
49437	7590	02/07/2006	EXAMINER	
ROCHE 11 SOUTH MERIDAN STREET INDIANAPOLIS, IN 46204			BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	
DATE MAILED: 02/07/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/631,339

Applicant(s)

WITTWER ET AL.

Examiner

William H. Beisner

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005 and 22 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-12 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-12 and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on 10/21/05 and 11/22/05 have been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

Art Unit: 1744

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985).

With respect to claim 21, the reference of von Behrens discloses a container (12) for holding a fluidic biological sample that includes a receiving portion (12a) and a reaction portion (12b). A liquid sample positioned within the receiving portion (12a) is capable of flowing into reaction portion (12b). As shown in Figure 1, the receiving portion (12a) has a volume greater than the reaction portion (12b). The reaction volume is not greater than 100 μ l (See column 4, lines 26-35). With respect to the recited thermal conductivity of the reaction portion, the reference of von Behrens discloses that the reaction portion (12b) is made of glass (See column 4, line 33) which is a material disclosed by the instant specification as a material with the claimed thermal conductivity (See page 53 of the instant specification). The reference of von Behrens discloses that the end of the reaction portion (12b) can be permanently sealed (See column 5, lines 57-67, and Figure 6). With respect to the claimed "wherein the closed end is formed for optical transmissibility through the closed end", the closed end of the reference of von Behrens as discussed previously is considered to meet this claim limitation since it is made of a transparent glass (See column 5, lines 57-67, Figure 6 and column 4, line 33).

The instant claim language employs the transitional language “consisting”. The device of von Behrens discloses the additional structure (11). However, this structure is only required when supporting the inner tube (12) within a centrifuge device.

As a result, it would have been obvious to one of ordinary skill in the art to provide the inner tube device (12) as a separate structure from the outer tube device for the known and expected result of using off the self-type of outer tubes (11) that would be provided separately from the inner tube device (12) prior to use. As a result, the inner tube structure (12) alone would meet the structure of instant claim 21. In the absence of further positively recited claim language defining the term “thin walled” capillary, the capillary tube disclosed by the reference of von Behrens is considered to be a “thin walled” capillary.

6. Claims 1-3, 5, 6, 9, 10, 11, 15, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Fite et al.(US 5,142,143).

The reference of von Behrens discloses a container (12) for holding a fluidic biological sample that includes a receiving portion (12a) and a reaction portion (12b). A liquid sample positioned within the receiving portion (12a) is capable of flowing into reaction portion (12b). As shown in Figure 1, the receiving portion (12a) has a volume greater than the reaction portion (12b). The reaction volume is not greater than 100 μ l (See column 4, lines 26-35). With respect to the recited thermal conductivity of the reaction portion, the reference of von Behrens discloses that the reaction portion (12b) is made of glass (See column 4, line 33) which is a material disclosed by the instant specification as a material with the claimed thermal conductivity (See page 53 of the instant specification). The reference of von Behrens discloses that the end of the

Art Unit: 1744

reaction portion (12b) can be permanently sealed (See column 5, lines 57-67, and Figure 6).

With respect to the claimed “wherein the closed end is formed for optical transmissibility through the closed end”, the closed end of the reference of von Behrens as discussed previously is considered to meet this claim limitation since it is made of a transparent glass (See column 5, lines 57-67, Figure 6 and column 4, line 33).

With respect to claims 1, 21 and 22, while the reference of vonBehrens discloses that portion (12b) of the inner tube device is a microhematocrit tube and can vary in volumetric capacity between 0.5 and 100 cubic millimeters (See column 5, lines 24-36), the reference is silent with respect to the wall thickness of the tube. Instant claims 1, 21 and 22 specify a “thin wall” or “0.1mm” thickness.

The reference of Fite et al. discloses that microhematocrit tubes having a wall thickness of 0.1mm is known in the art (See column 11, lines 18-24).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the microhematocrit tube disclosed by the reference of Fite et al. as element (12b) of the reference of von Behrens for the known and expected result of providing an art recognized microhematocrit tube within the system of von Behrens as is required of the device of the primary reference.

The instant claim language employs the transitional language “consisting”. The device of von Behrens discloses the additional structure (11). However, this structure is only required when supporting the inner tube (12) within a centrifuge device.

As a result, it would have been obvious to one of ordinary skill in the art to provide the inner tube device (12) as a separate structure from the outer tube device for the known and expected result of using off the self-type of outer tubes (11) that would be provided separately from the inner tube device (12) prior to use. As a result, the inner tube structure (12) alone would meet the structure of instant claim 21. In the absence of further positively recited claim language defining the term “thin walled” capillary, the capillary tube disclosed by the reference of von Behrens is considered to be a “thin walled” capillary.

With respect to claim 2, the reference of von Behrens discloses that the upper section or receiver portion (12a) is made of plastic (See column 5, lines 40-46).

With respect to claim 3, the reference of von Behrens discloses that the upper section or receiver portion (12a) is funnel shaped (See Figure 1).

With respect to claims 5, 9, 10 and 19, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to optimize the dimensions of the tube based merely on the desired volume of liquid to be drawn into the capillary vessel.

With respect to claim 6, the reaction portion (12b) is made of glass which is transparent.

With respect to claim 11, the specifics of the interface between the funnel-shaped upper portion (12a) and the lower portion (12b) would have been well within the purview of one having ordinary skill in the art while maintaining a fluid seal between the separate elements (See column 5, lines 33-47).

With respect to claim 15, the reaction portion has a v:sa ratio of less than 1mm or 0.25mm (See column 4, lines 26-35).

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Fite et al.(US 5,142,143) taken further in view of Gerarde (US 3,518,804).

The combination of the references of von Behrens and Fite et al. has been discussed above.

Claim 4 differs by reciting that the receiver portion includes a plug.

The reference of Gerarde discloses that it is known in the art to seal the receiver portion (12) of the device that is similar in structure to the device of the modified primary reference with a plug (24) (See Figure 3).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide the receiving section (12a) of the modified primary reference with a plug for the known and expected result of sealing the open end of the tube during storage of the device to protect the interior from contamination and/or protect a contained sample from contamination, exposure and/or leakage from the container.

8. Claims 12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over von Behrens (US 3,914,985) in view of Fite et al.(US 5,142,143) taken further in view of Hawes (US 3,556,659).

The combination of the references of von Behrens and Fite et al. has been discussed above.

While the reference of von Behrens discloses that the end of the tube may be sealed (See column 5, lines 63-65 and Figure 6), the reference does not disclose that the sealed end is flat or permits light having a wavelength of about 400nm to about 800nm.

The reference of Hawes discloses that it is conventional in the art to seal the end of a capillary tube such that it forms a flat tip (See Figures 2a and 3-5).

In view of this teaching, it would have been obvious to one having ordinary skill in the art at the time the invention was made to seal the end of the capillary using forming a flat tip as suggested by the reference of Hawes for the known and expected result of providing an alternative means recognized in the art to seal the end of a capillary tube. The method disclosed by the reference of Hawes provides a capillary tube that is capable of being optically interrogated through the end of the capillary tube. Additionally, since glass is employed, it would be capable of passing light in the range of 400nm to 800nm as required of the instant claims.

Response to Arguments

9. With respect to the rejection of claims 7-9, 15, 16 and 21 under 35 USC 102 over the reference of von Behrens, Applicants' amendments and associated comments (See page 5 of the response dated 11/22/05) are persuasive to overcome the rejection of record. However, a new grounds of rejection has been made with respect to claim 21 under 35 USC 103 over the reference of von Behrens.

10. With respect to the rejection of claims 1-6 and 19 under 35 USC 103 over the combination of the references of Gerarde and Gerarde, Applicants amendments and associated

Art Unit: 1744

comments (See pages 6-7 of the response dated 11/22/05) are persuasive to overcome the rejection of record. However, a new grounds of rejection has been made under 35 USC 103 over the combination of the references of von Behrens and Fite et al.

11. With respect to the rejection of claims 7, 9-12, 15-18 and 20-22 under 35 USC 103 over the combination of the references of Gerarde, Gerarde and Hawes, Applicants amendments and associated comments (See pages 7-8 of the response dated 11/22/05) are persuasive to overcome the rejection of record. However, a new grounds of rejection has been made under 35 USC 103 over the combination of the references of von Behrens and Fite et al.

12. With respect to the rejection of claim 19 under 35 USC 112, first paragraph, Applicants comments (See pages 9-10 of the response dated 11/22/05) are persuasive to overcome the rejection of record.

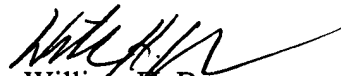
Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1744

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB